

TO: Distribution  
FROM: Victor Han  
SUBJECT: EPA Communications Plan

DATE: February 18, 1994

Executive Summary

The contents of this binder are draft communications plans and documents for use when the court renders its judgment on the pending motion to dismiss.

In the case of a win or mixed decision, we have agreed to a low key approach with certain proactive options that would be decided upon once the court rules. At its core, the plan calls for reactive responses to media regarding the judgment and a reiteration of why we filed suit in the first place.

In the case of a loss, especially with little or no notice, geographical logistics do not allow for an ideal scheme with all spokespeople present in a central location backing each other up for print and satellite. As a result, the optimum measures we can put in place is assign satellite work to S. Parrish and print to B. Weber/D. Donohue wherever they happen to be at the time the decision is handed down. This is the optimum in our view though hardly perfect. To assemble at a central location would have too many people traveling when we need them most.

Please review these materials and contact Jack Lenzi or Vic Han with comments, concerns, additions or for explanations.

Distribution:  
D. Donohue  
L. Dreyer  
M. Payne-Ellis  
T. Humber  
E. Merlo  
S. Parrish  
C. Wall  
R. Weber

Encl.

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I. PLAN

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**EPA LAWSUIT COMMUNICATIONS PLAN**  
**IMMEDIATE IMPLEMENTATION MEASURES**

- **NOTE:** The following provides contingencies for implementing our communications plan without prior notice of the decision. Even if we receive prior notice of when the court will rule, we will have no information on the nature of the ruling until it actually happens.

Therefore, it is recommended that we be prepared for the worst case scenario. The only difference with prior notice is that we will have a bit more time to discuss key points and come to some conclusions prior to the ruling day.

**I. COURT RULES WITHOUT ORAL ARGUMENT**

- A. PLAINTIFFS WIN: Communications plan requires low-key response.**

**Court Rules Without Notice in Support of Plaintiffs:**

1. Designated RJR paralegal will check court's filings everyday.
2. RJR will immediately contact Bob Weber, Dan Donahue, Steve Parrish, Jack Lenzi and/or Vic Han. In the meantime, RJR will obtain a copy of the ruling and fax it to Weber, Bond and Lenzi.
3. Han and/or Lenzi will notify Bond. All parties will review ruling and prepare for a conference call one hour from receipt of the ruling.
4. Conference call will be initiated by Philip Morris (via ATT) and will include Weber, Bond, Parrish, Donahue, PM Team, and RJR Team. Points of discussion will be:
  - Review of ruling
  - Review and adjustment of statements
  - Review of PR plan (VNR, radio actualities, op-eds),
  - Reaction to and handling of media calls
5. For PM, Brendan McCormick and Tara Carraro will split the contact list and call all key PM personnel and vendors (Reuters, Burson). For RJR, Maura Payne-Ellis will call all appropriate personnel.

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6. An agreement has been made that plaintiffs will withhold comment on the ruling until all are in agreement as to who should deliver the first response. As a proviso for wire services who are filing, all parties should comment as follows:

"We cannot comment without reviewing the court's decision." If the reporter volunteers the ruling information, comment should be. "I haven't seen the ruling myself, however, I'll be happy to comment as soon as I've had an opportunity to review it."
7. If agreed upon, a joint (PM & RJR) press release will be issued to PR Newswire with ruling, our position on the ruling and our position on the case.
8. If RJR receives media calls they will elect to have Donahue/Weber answer and then to Fred Bond (in southern states). They may also elect to refer to Steve Parrish.
9. If PM receives media calls they will screen the call, have Steve Parrish comment and then refer to Bob Weber/Dan Donahue and then to Fred Bond (in southern states).
10. Talking Points will be faxed to all PM Regional Directors by Mary Ellen Moore and Terri Popoli as an FYI and for use with legislators and consultants. All media calls to PM should be referred to the NYO Media Affairs office.
11. If during the conference call, a decision is made to release radio actualities and VNR/B-roll, Tara Carraro will notify Reuters.
12. If agreed, Burson DC will overnight win version op-eds to the top 100 newspapers and top 25 magazines.
13. If necessary, the 26th Floor presentation room will be turned into a "War Room" for Philip Morris personnel.

- B. **PLAINTIFFS LOSE:** Communications plan requires an all-out effort.

**Court Rules Without Notice Against Plaintiffs:**

1. Designated RJR paralegal will check court's filings everyday.
2. RJR will immediately contact Bob Weber, Dan Donahue, Steve Parrish, Jack Lenzi and/or Vic Han. In the meantime, RJR will obtain a copy of the ruling and fax it to Weber, Bond and Lenzi.
3. Han and/or Lenzi will notify Bond. All parties will review ruling and prepare for a conference call one hour from receipt of the ruling.
4. Conference call will be initiated by Philip Morris (via ATT) and will include Weber, Bond, Parrish, Donahue, PM Team, and RJR Team. Points of discussion will be:
  - Review of ruling
  - Review and adjustment of statements
  - Review of PR plan (VNR, radio actualities, op-eds).
  - Reaction to and handling of media calls
  - **Satellite Media Tour:** If agreed, Steve Parrish will be principal spokesperson with Bob Weber as backup if Parrish is not reachable.
  - **Media Calls:** If agreed, Bob Weber will be lead spokesperson with print media with Charles Wall as backup if Weber must fill in for Parrish with broadcast.
  - **Bond** will be referred to for print if southern POV is required.
  - **Press Conference:** If agreed, press conference will be held either in Washington D.C. or New York. Location will be decided at this time. Washington is preferable. Persons to attend will also be determined.
  - **Facility** for press conference will be determined and depending on the city the following will be responsible: NY - PM, Washington - Burson.
  - **A "War Room"** must be set up in the press conference city preferably at the following locations: NY - PM NYO, Washington - PM or Burson.

-- A decision will also be made as to if and when the following will be released: VNR, radio actualities, op-eds, media advisory.

5. For PM, Brendan McCormick and Tara Carraro will split the contact list and call all key PM personnel and vendors (Reuters, Burson). For RJR, Maura Payne-Ellis will call all appropriate personnel.
6. An agreement has been made that plaintiffs will withhold comment on the ruling until all are in agreement as to who should deliver the first response. As a proviso for wire services who are filing, all parties should comment as follows:

"We cannot comment without reviewing the court's decision." If the reporter volunteers the ruling information, comment should be. I haven't seen the ruling myself, however, I'll be happy to comment as soon as I've had an opportunity to review it."
7. If agreed upon, a joint (PM & RJR) press release will be issued to PR Newswire with ruling, our position on the ruling and our position on the case.
8. Talking Points will be faxed to all PM Regional Directors by Mary Ellen Moore and Terri Popoli as an FYI and for use with legislators and consultants. All media calls to PM should be referred to the NYO Media Affairs office.
9. For assistance with travel arrangements, (if necessary) all parties can contact Mary Ellen Moore or Terri Popoli with Philip Morris. A list of recommended hotels in each city is provided and the Philip Morris Travel emergency number is (212) 847-0242 and the PM code is S-C3GO.
10. If agreed, Tara Carraro will notify Reuters to release pre-taped radio actualities and VNR/B-roll immediately.
11. Press Conference, if it is agreed that we go ahead, will be set for the following morning and all attempts will be made to get all spokesmen to Washington. Pre-produced press kits will be distributed.
12. If a press conference is agreed upon, Burson will issue media alert announcing press conference.
13. If agreed, Burson DC will overnight loss version op-eds to the top 100 newspapers and top 25 magazines.
14. **The 26th Floor presentation room will be turned into a "War Room" for Philip Morris personnel.**

Source: <https://www.industrydocuments.ucsf.edu/docs/sgbj0000>



- C. If court rules without oral argument, but with notice, both the win and loss plans remain the same, except the conference call can take place prior to the ruling and solid plans developed for both scenarios. In the unlikely event that we are given 2-3 days notice, we can arrange a conference call and proceed with the same elements but with the additional option of bringing everyone to a central location.

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## II. RESPONSE TO COURT ANNOUNCEMENT THAT IT WILL HEAR ORAL ARGUMENT

1. Response should be low-key and reactive in nature.
2. Weber will be primary spokesperson with Parrish, Bond and Donahue available as backup.
3. Key Message Points: We're pleased that the court has chosen to hear oral arguments in our case and we look forward to responding to the EPA's filing of a motion to dismiss which is a procedural technicality only." (refer to section 2 of binder).
4. Press releases will be prepared and kept on hand by RJR and PM to fax to media and other appropriate audiences.

## III. DAY OF ORAL ARGUMENT

1. Response should be low-key and reactive in nature.
2. Best scenario would be to utilize courthouse steps with Weber as the primary spokesperson with Parrish, Donahue and Bond present for backup.
3. Pre-written talking points will be used that reiterate the most important points in the case and speak favorably to the pending decision.
4. Key Message Points: "We are pleased with the presentation of our case and Judge Osteen's interest in, and insightful questions on a number of issues. We are optimistic that the court will render a favorable decision and look forward to a full review of the EPA's science and methodology." (refer to section 2 of binder).
5. Press releases will be prepared and kept on hand by RJR and PM to fax to media and other appropriate audiences.
6. A communications team (Vic Han or Jack Lenzi) will be present to observe and extract key messages from the arguments of both parties for possible use.

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IV. COURT RULES WITH ORAL ARGUMENT:

- A. PLAINTIFFS WIN: Communications plan requires low-key response.

Court Rules Without Notice in Support of Plaintiffs:

1. Same plan as a win without oral argument.

- B. PLAINTIFFS LOSE: Communications plan requires an all-out effort.

Court Rules Without Notice Against Plaintiffs:

1. Same plan as a loss without oral argument

- C. If court rules without oral argument, but with notice, both the win and loss plans remain the same, except the conference call can take place prior to the ruling and solid plans developed for both scenarios. In the unlikely event that we are given 2-3 days notice, we can arrange a conference call and proceed with the same elements but with the additional option of bringing everyone to a central location.

V. POSSIBLE SCENARIOS AND COMMENTS

- **Morning ruling without notice:** Not ideal because we'll have to scramble, but still gives us some time to prepare especially in a loss situation. Radio actualities and VNR/B-roll are available for immediate use as are press statements. A satellite media tour remains a possibility. We have the day to plan a press conference for the following day and get all necessary parties to their assigned locations.
- **Afternoon ruling without notice:** Timing will be tight and we may have to hold the press conference during the afternoon of the following day in order to coordinate the logistics properly. This will still be OK, however, because we'll make media deadlines as long as we don't go past 3:00 pm or 3:30 pm. Again, press statements, radio actualities and VNR/-B-roll are all available along with the satellite media tour.
- **Morning or afternoon ruling with notice:** It presents a greater window of opportunity to organize our efforts and implement our plan.
- **Late Friday ruling:** In a win situation this is not the worst possible scenario because we want to low key it anyway. We can issue statements and be prepared to react to any incoming media calls and we can also release VNRs and B-roll as well as radio actualities.

In a loss situation it becomes more complicated, because the issue of a press conference and when to hold it becomes key. This does work both ways, however. Our opponents will receive less coverage as well on a weekend.

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**II TALKING POINTS**

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ADVANCE COMMUNICATIONS ACTIVITYKey Message Point:

"The issue currently before the Court is limited to the very narrow, legal technicality of a Motion to Dismiss, not the actual merits of the case. By using this procedural tactic, the EPA is attempting to have the case dismissed without a thorough judicial review of its conduct. We will encourage the Court to deny this motion and proceed to trial where the EPA's violations of scientific methodology and its attempt to supersede its own regulatory authority can be fully reviewed.

We look forward to a trial on the specific issues because the EPA's classification of ETS is simply not justified by the available science.

Twenty-four of the thirty studies reviewed by the EPA do not support the agency's conclusion. Those twenty-four reported no statistically significant association between ETS and lung cancer.

The EPA relied on 11 studies conducted in the US. to estimate the relative risk associated with ETS: not one of these studies originally achieved statistical significance overall. The EPA forced a conclusion of increased risk by lowering the standards used by the researchers-- this is an unprecedented action that merits Court review.

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The EPA ignored one of the largest and most recent studies on ETS, funded in part by the National Cancer Institute, which reported no overall statistically significant association between ETS and lung cancer.

The EPA lacks the legal authority to classify ETS as a Group A carcinogen; in fact the Radon Act expressly prohibits the EPA from carrying out "any regulatory program." EPA's actions were intended to achieve a substantial regulatory effect, in violation of law."

(Statements will be tailored to include direct quotes from key spokespersons.)

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COMMUNICATIONS ACTIVITY  
PRIOR TO ORAL ARGUMENT

Key Message Point:

"The issue currently before the Court is limited to the very narrow, legal technicality of a Motion to Dismiss, not the actual merits of the case. By using this legal tactic, the EPA is attempting to have the case dismissed without a thorough judicial review of its conduct. We will urge the Court to deny this motion and proceed to trial where the EPA's violations of scientific methodology and its attempt to supersede its own regulatory authority can be fully reviewed.

We look forward to a trial on the specific issues because the EPA's classification of ETS is simply not justified by the available science.

Twenty-four of the thirty studies reviewed by the EPA do not support the agency's conclusion. Those twenty-four reported no statistically significant association between ETS and lung cancer.

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Statements will be tailored to include direct quotes from key spokespersons.

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DAY OF ORAL ARGUMENTKey Message Point:

"We are pleased with the presentation of our case and Judge Osteen's interest in, and insightful questions on, a number of issues. We are optimistic the Court will render a favorable decision and look forward to a full review of the EPA's science and methodology.

We look forward to a trial on the specific issues because the EPA's classification of ETS is simply not justified by the available science.

Twenty-four of the thirty studies reviewed by the EPA do not support the agency's conclusion. Those twenty-four reported no statistically significant association between ETS and lung cancer.

The EPA relied on 11 studies conducted in the US. to estimate the relative risk associated with ETS; not one of these studies originally achieved statistical significance overall. The EPA forced a conclusion of increased risk by lowering the standards used by the researchers-- this is an unprecedented action that merits Court review.

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(Statements will be tailored to include direct quotes from key spokespersons.)

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## PLAINTIFFS WIN. MOTION DENIED

### Key Message Points:

"We are pleased with the decision reached today by the District Court/Judge Osteen. We have maintained from the beginning that the EPA's actions should be reviewed on the merits and the Court agreed with our position. The EPA has failed in its initial attempts to avoid judicial review of its actions.

We look forward to a trial on the specific issues because the EPA's classification of ETS is simply not justified by the available science.

Twenty four of the thirty studies reviewed by the EPA do not support the agency's conclusion. Those twenty-four reported no statistically significant association between ETS and lung cancer.

The EPA relied on 11 studies conducted in the US. to estimate the relative risk associated with ETS; not one of these studies originally achieved statistical significance overall. The EPA forced a conclusion of increased risk by lowering the standards used by the researchers-- this is an unprecedented action that merits Court review.

The EPA ignored one of the largest and most recent studies on ETS, funded in part by the National Cancer Institute, which reported no overall statistically significant association between ETS and lung cancer.

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The EPA lacks the legal authority to classify ETS as a Group A carcinogen; in fact the Radon Act expressly prohibits the EPA from carrying out any regulatory program. EPA's actions were intended to achieve a substantial regulatory effect, in violation of law.

(Statements will be tailored to include direct quotes from key spokespersons.)

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PLAINTIFFS LOSE, MOTION GRANTEDKey Message : Points:

"The EPA has temporarily avoided judicial review of its actions when the District Court granted it Motion to Dismiss. Let's be clear on one critical point: This was not a decision on the merits of the case, nor a vindication of the science, methodology, or conclusions of the EPA. This is a decision on a technical, legal procedural issue only.

We will appeal this decision because (the EPA acted outside its authority, acted in contradiction to its own procedures, acted in an arbitrary and capricious manner and in violation of our due process rights - Subject to revision)

We look forward to a successful appeal and a full review of the EPA's actions which are based on and include:

- Twenty-four of the thirty studies reviewed by the EPA do not support the agency's conclusion. Those twenty-four reported no statistically significant association between ETS and lung cancer.
- The EPA relied on 11 studies conducted in the US. to estimate the relative risk associated with ETS: not one of these studies originally achieved statistical significance overall. The EPA forced a conclusion of increased risk by lowering the standards used by the researchers-- this is an unprecedented action that merits Court review.

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- The EPA ignored one of the largest and most recent studies on ETS, funded in part by the National Cancer Institute, which reported no overall statistically significant association between ETS and lung cancer.

The EPA lacks the legal authority to classify ETS as a Group A carcinogen; in fact the Radon Act expressly prohibits the EPA from carrying out "any regulatory program." EPA's actions were intended to achieve a substantial regulatory effect, in violation of law."

Statements will be tailored to include direct quotes from key spokespersons.)

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## SPLIT DECISION

### Key Message Point:

We are pleased that the Court did not accept the EPA's motion and dismiss the case. Though the Court did dismiss XXX claim(s), it recognized the importance of the remaining claims and the need to review EPA's conduct. We intend to vigorously pursue our claims and will evaluate our appeal options as to those claims the Court has dismissed. We remain confident that we will prevail in this action.

We look forward to a trial on the specific issues because the EPA's classification of ETS is simply not justified by the available science.

Twenty-four of the thirty studies reviewed by the EPA do not support the agency's conclusion. Those twenty-four reported no statistically significant association between ETS and lung cancer.

The EPA relied on 11 studies conducted in the US. to estimate the relative risk associated with ETS: not one of these studies originally achieved statistical significance overall. The EPA forced a conclusion of increased risk by lowering the standards used by the researchers-- this is an unprecedented action that merits Court review.

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The EPA ignored one of the largest and most recent studies on ETS, funded in part by the National Cancer Institute, which reported no overall statistically significant association between ETS and lung cancer.

The EPA lacks the legal authority to classify ETS as a Group A carcinogen; in fact the Radon Act expressly prohibits the EPA from carrying out "any regulatory program." EPA's actions were intended to achieve a substantial regulatory effect, in violation of law.

(Statements will be tailored to include direct quotes from key spokespersons.)

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WIRE SERVICE PROVISIO

Key Message Point:

"We cannot comment without reviewing the court's decision." If the reporter volunteers the ruling information, comment should be. "I haven't seen the ruling myself, however, I'll be happy to comment as soon as I've had an opportunity to review it."

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TOBACCO STATES WIN RESPONSESKey Message Points:

"We're delighted by this ruling which forces EPA to defend its conduct in court. In a court of law, rules of science and evidence will control, not EPA's predetermined and biased policies.

The livelihood of tens-of-thousands of tobacco farmers should not be subjected to the political whims of a government agency. We are pleased by the court's decision and we hope our lawsuit will end the EPA's practice of basing public policy on politics rather than sound science.

We look forward to a trial on the specific issues because the EPA's classification of ETS is simply not justified by the available science.

Twenty-four of the thirty studies reviewed by the EPA do not support the agency's conclusion. Those twenty-four reported no statistically significant association between ETS and lung cancer.

The EPA relied on 11 studies conducted in the US. to estimate the relative risk associated with ETS; not one of these studies originally achieved statistical significance overall. The EPA forced a conclusion of increased risk by lowering the standards used by the researchers-- this is an unprecedented action that merits Court review.

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The EPA ignored one of the largest and most recent studies on ETS, funded in part by the National Cancer Institute, which reported no overall statistically significant association between ETS and lung cancer.

The EPA lacks the legal authority to classify ETS as a Group A carcinogen; in fact the Radon Act expressly prohibits the EPA from carrying out "any regulatory program." EPA's actions were intended to achieve a substantial regulatory effect, in violation of law."

(Statements will be colored to include direct quotes from key spokespersons.)

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TOBACCO STATES LOSS RESPONSESKey Message Points:

"Without question, the EPA's report jeopardizes the future of tens-of-thousands of tobacco farmers. The EPA can not be allowed to continue making public policy decisions based on politics rather than science.

The court's ruling is strictly technical in nature. If and when we can force the EPA to face the merits of our case in court, we're confident that EPA's conduct will be exposed for what it is, predetermined EPA policy and not sound science.

Twenty-four of the thirty studies reviewed by the EPA do not support the agency's conclusion. Those twenty-four reported no statistically significant association between ETS and lung cancer.

The EPA relied on 11 studies conducted in the US. to estimate the relative risk associated with ETS; not one of these studies originally achieved statistical significance overall. The EPA forced a conclusion of increased risk by lowering the standards used by the researchers-- this is an unprecedented action that merits Court review.

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The EPA ignored one of the largest and most recent studies on ETS, funded in part by the National Cancer Institute, which reported no overall statistically significant association between ETS and lung cancer.

The EPA lacks the legal authority to classify ETS as a Group A carcinogen; in fact the Radon Act expressly prohibits the EPA from carrying out "any regulatory program." EPA's actions were intended to achieve a substantial regulatory effect, in violation of law.

(Statements will be tailored to include direct quotes from key spokespersons.)

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For Immediate Release  
(Date)

Contact:

### Federal Court Rejects EPA's Motion to Dismiss Lawsuit

(CITY), DATE -- A federal court in Winston Salem, N.C., has rejected a motion filed by the U.S. Environmental Protection Agency to dismiss a lawsuit filed against the agency by a group of tobacco growers and businesses in June 1993. The lawsuit, which will now go to trial, seeks to have the EPA's report on and classification of environmental tobacco smoke (ETS) declared null and void.

"Not only did the EPA ignore its own scientific guidelines and manipulate data in conducting its risk assessment on ETS, it also overstepped its regulatory authority," said Robert Weber, an attorney with Jones, Day, Reavis and Pogue representing R.J. Reynolds, one of the plaintiffs. "We're delighted by the ruling that now forces the EPA to defend its conduct in court where the rules of science and evidence will control, not the agency's predetermined and biased policies."

"The livelihoods of tens of thousands of tobacco farmers should not be subjected to the political whims of a government agency," said Fred Bond, chief executive officer of the Flue-Cured Tobacco Cooperative Stabilization Corporation, which also is a plaintiff in the lawsuit. "We hope our case will end the EPA's practice of basing public policy on politics rather

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than sound science."

R.J. Reynolds and the Cooperative were joined by The Council for Burley Tobacco Inc., Gallins Vending Company, Universal Leaf Tobacco Company Inc. and Philip Morris Inc. in filing the suit June 22, 1993, in the U.S. District Court for the Middle District of North Carolina.

In their complaint, the plaintiffs state that the EPA, in classifying ETS as a "Group A" carcinogen, had:

- o used faulty science and improper scientific procedures to arrive at its conclusion;
- o manipulated and "cherry-picked" scientific data, ignoring recent studies that contradicted its conclusions; and
- o used scientific assumptions and methodologies not generally accepted by the scientific community or even the agency itself in other risk assessments it conducted in the past.

In addition, the plaintiffs have asked the court to find that the EPA exceeded its statutory authority in concluding that ETS is a known human carcinogen and failed to follow its own guidelines for conducting risk assessments and to declare the risk assessment null and void.

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"The EPA ignored its own guidelines and manipulated data to get a pretermained conclusion," said Steve Parrish, Senior Vice President and General Counsel for Philip Morris U.S.A. "That's wrong as a matter of law and as a matter of science. The court's ruling to dismiss the EPA's claim of immunity is the first step in setting the record straight."

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IV PRESS RELEASE-LOSS

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DRAFT

For Immediate Release  
(Date)

Contact: \_\_\_\_\_

### Tobacco Group Considering Appealing Court Ruling

(CITY), DATE -- Plaintiffs in a lawsuit against the U.S. Environmental Protection Agency (EPA) are considering an appeal of today's ruling by a federal court in North Carolina in favor of the agency's claim of immunity from judicial review. The lawsuit against the EPA, which was filed in June 1993 by a group of tobacco growers and businesses, sought to have the agency's report on and classification of environmental tobacco smoke (ETS) declared null and void.

"In conducting the risk assessment on ETS, the EPA ignored its own guidelines and manipulated data to get the conclusion it wanted," said Steve Parrish, Senior Vice President and General Counsel for Philip Morris U.S.A., a plaintiff in the lawsuit. "That's wrong as a matter of law and as a matter of science. Consequently, we are seriously considering an appeal."

Robert Weber, an attorney with Jones, Day, Reavis and Pogue representing R.J. Reynolds, one of the plaintiffs, expressed disappointment in the court's ruling, but noted that its decision was strictly technical in nature. "The court's ruling was not based on the merits of our case and in no way validates the EPA's report on ETS," Weber said. "If and when the EPA is forced to face the merits of our case in court, we're confident

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that the agency's conduct will be exposed for what it is --  
predetermined policy and not sound science."

Philip Morris Inc. and R.J. Reynolds were joined by the  
Flue-Cured Tobacco Cooperative Stabilization Corporaton, The  
Council for Burley Tobacco Inc., Gallins Vending Company and  
Universal Leaf Tobacco Company Inc. in filing the suit June 22,  
1993, in the U.S. District Court for the Middle District of  
North Carolina. In their complaint, the plaintiffs stated that  
the EPA, in classifying ETS as a "Group A" carcinogen, had:

- o used faulty science and improper scientific procedures to  
arrive at its conclusion;
- o manipulated and "cherry-picked" scientific data, ignoring  
recent studies that contradicted its conclusions; and
- o used scientific assumptions and methodologies not generally  
accepted by the scientific community or even the agency  
itself in other risk assessments it conducted in the past.

In addition, the plaintiffs asked the court to find that the EPA  
exceeded its statutory authority in concluding that ETS is a  
known human carcinogen and failed to follow its own guidelines  
for conducting risk assessments and to declare the risk  
assessment and classification null and void.

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"Without question, the EPA's report jeopardizes the future of tens of thousands of tobacco farmers," said Fred Bond, chief executive officer of the Flue-Cured Tobacco Cooperative Stabilization Cooperation. "And we will continue our fight to prevent the EPA from making public policy decisions based on politics rather than science."

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V PRESS PACKET

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DRAFT

DISCUSSION POINTS RE: EPA RISK ASSESSMENT SCIENTIFIC ISSUES

1. Isn't it a fact that 24 of the 30 studies reviewed by the EPA, and on which it based its risk assessment calculations, originally reported no statistically significant overall increased risk for spousal smoking?

Discussion: The EPA should respond in the affirmative.

The concept of "statistical significance" is important because it permits a scientist to infer either that the data in a study support or do not support a given hypothesis. For the studies on spousal smoking and lung cancer, the data in 24 of 30 studies reviewed by the EPA are compatible with the hypothesis that there is no overall association between spousal smoking and lung cancer.

Typically, when results do not achieve statistical significance, further analysis of the data is not meaningful or productive. Apparently, the EPA does not ascribe to this accepted statistical principle. While data from the six remaining statistically significant studies permit the scientist to reject the hypothesis of no association, the scientist must further investigate whether the statistically

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If the data on workplace exposures are pooled in a meta-analysis, the risk estimate is below 1.00 (unity), which indicates no positive association between reported workplace exposures to ETS and lung cancer in nonsmokers. However, the Risk Assessment did not consider those data.

4. Isn't it a fact that the EPA omitted from its ETS risk calculation data from the NCI-funded Brownson, et al., study, one of the largest and most recent studies on ETS exposure and lung cancer, which found no increase in risk from exposure to ETS?

Discussion: The EPA should confirm that it has not included the Brownson study in its calculations.

This case-control study is among the largest conducted on reported ETS exposure and lung cancer incidence. It includes 432 "lifetime" nonsmokers and 186 exsmokers, and 1,402 controls.

- \* An OR of 1.0 (95% CI 0.8-1.2) was reported for spousal smoking in nonsmokers (218 cases and 598 controls). This odds ratio is not statistically significant.

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The EPA has established a precedent-shattering framework for the ETS and other future risk assessments. As proclaimed by Dr. William Farland, from EPA's Office of Health and Environmental Assessment to the Science Advisory Board's IAQTHEC meeting on July 21, 1992:

This (the ETS risk assessment) is a high visibility assessment . . . because of its implications for the future of the way we do business. (Meeting transcript, at I-31.)

\* \* \*

First of all, we have a focus on human data which is fairly unique in terms of dealing with environmental pollutants. (Meeting transcript, at I-33.)

\* \* \*

Another fairly unique situation with regard to environmental risk assessments is we've taken the opportunity to use some new techniques, meta-analysis for lung cancer, that we think will be important to us in terms of combining information from various studies as we do risk assessments in the future. (Meeting transcript, at I-34 .)

\* \* \*

So, we think that there are some interesting and important features and an opportunity to do some innovative risk assessment work in this particular assessment. (Emphasis added.) (Meeting transcript, at I-35.)

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studies are to be considered. The EPA's current strategy to classify ETS as a Group A carcinogen based solely upon epidemiologic studies would have failed had they carefully adhered to their own guidelines.

7. Isn't it true that if the EPA were to subject chlorinated water, the ordinary tap water consumed by most Americans, to the exact same methodology applied to ETS, chlorinated water would also be a Group A carcinogen?

Discussion: EPA must clearly answer yes.

According to the results of a meta-analysis of reported data on the chlorination of water and chlorination by-products and cancer incidence, published in the American Journal of Public Health (July 1992), the authors reported that "a sample meta-analysis of all cancer sites yielded a relative risk estimate for exposure to chlorination by-products of 1.15." These results were statistically significant, as were results reported for "organ-specific neoplasms" such as bladder cancer and rectal cancer. The meta-analysis was based upon the adjusted relative risk estimates from epidemiologic

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spicy foods, will affect risk estimates for nonsmokers married to smokers. Other studies suggest that diet is an independent risk factor for lung cancer.

9. Isn't it true that this is the first time the EPA has classified any substance a Group A carcinogen based on such weak epidemiological data and without corroborating animal data?

Discussion: EPA must respond in the affirmative.

This is the first EPA risk assessment based solely upon epidemiologic data in which a substance has been designated a Group A carcinogen. Public comments on the risk assessment by scientists pointed out that the epidemiologic data on spousal smoking, when taken as a whole, do not convincingly support a Group A carcinogen classification. Most of the studies are not statistically significant, and study biases and confounders (e.g., occupation, diet, heredity, etc.) were not effectively ruled out as contributing factors to the reported associations between spousal smoking and lung cancer. The summary risk estimate achieved by combining those studies

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scientifically accepted 95% level for statistical significance to a 90% level.

11. Why has the EPA undertaken a re-analysis of the published data on ETS and lung cancer?

Discussion: The EPA will argue that its re-analysis of the data was necessary in order to determine more precisely an effect from ETS exposures.

For example, the EPA will undoubtedly point to the "profound effect" on lung cancer incidence from reportedly "high exposures" to ETS that it discovered during re-analysis of the data. Seventeen of the 30 studies examined by the EPA present data on individuals who reported "high" exposures to ETS. The EPA re-analyzed those data and claimed that they displayed a clear, positive trend, i.e., every one of the high exposure groups in the 17 studies exhibited an increased risk for lung cancer.

While this argument may, at face value, appear compelling, it is a clear example of what statisticians call "data-dredging." It is important to note that the raw data which provide the basis

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applies meta-analysis, makes background adjustments for exposure to ETS, changes statistical procedures, and re-analyzes high exposure level data to support its position.

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## SUMMARY OF CRITICISMS ON EPA RISK ASSESSMENT

The EPA Risk Assessment includes a selective review of the literature on mainstream smoke, coupled with a series of unfounded and demonstrably false assumptions.

- The Risk Assessment's "hazard identification" does not review published data on the physical and chemical characteristics of ETS and relies upon the assumption that mainstream smoke and ETS are similar substances.
- The EPA document fails to recognize that the tobacco smoke to which the nonsmoker is exposed differs both physically and quantitatively from mainstream smoke.<sup>1-8</sup>

The Risk Assessment does not address these differences and does not attempt any chemical or quantitative comparison between ETS and mainstream smoke.

ETS is a highly diluted, aged and chemically altered mixture of sidestream smoke (the smoke emitted from the burning end of the cigarette) and exhaled mainstream smoke. The chemical composition of this mixture changes as it ages and interacts with other materials present in the room air.

- The active smoking data presented by the EPA are not relevant to the suspected route of exposure for ETS or, given the

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i.e., inhalation to the lung, or to the disease endpoint under discussion (lung cancer).

- Animal inhalation studies employing fresh sidestream smoke and ETS were similarly not discussed in the Risk Assessment.

All three publicly available studies to date have reported no statistically significant increased incidence of tumors in animals exposed to ETS compared with controls.<sup>11-14</sup>

Moreover, the Risk Assessment fails to recognize that none of the lifetime, "whole smoke" exposure studies on animals, originally designed to assess possible biological effects from mainstream smoke exposures, have reported the induction of lung carcinomas via inhalation.

The Risk Assessment fails to reference a number of actual studies comparing levels of mutagens and other genotoxic markers in the body fluids of exposed and non-exposed nonsmokers.<sup>15-24</sup>

- The results of those studies suggest no statistically significant increases in mutagenic activity in the body fluids of nonsmokers exposed to realistic levels of ETS compared with nonsmokers who are not exposed.



- The EPA's meta-analysis violated a fundamental principle of meta-analysis: it did not aggregate similar data. For example, all of the studies employed different questionnaires and different assessments of past exposure; five of the studies failed to match cases with controls; and the criteria for control selection were different in each study.<sup>28</sup>
- If the EPA had sought to address the lack of statistical power in some of the studies, it could have placed less emphasis on those studies and more upon the individual studies with sufficient statistical power. The individual studies with sufficient power do not report overall point estimates that achieve statistical significance.
- The statistical power question notwithstanding, the EPA has not addressed the issue of the aggregation of dissimilar data in its meta-analysis. Moreover, even the "common thread" identified by the EPA as justification for meta-analysis, spousal smoking, is defined differently across studies.

The EPA relied on a cumulative risk estimate derived from the meta-analysis of 11 U.S. epidemiologic studies of spousal smoking for its classification of ETS as a known human carcinogen.<sup>29-39</sup>

lung cancer. Reported overall point estimates in six non-U.S. studies are statistically significant, but the EPA did not ascertain whether or not these purported associations are due to some feature that is coincidental to "marriage to a smoker" (e.g., common diet, occupational exposures, socioeconomic status and other lifestyle characteristics).

The EPA intentionally lowered the confidence interval reported in the individual epidemiologic studies from 95% to 90% in an apparent attempt to rule out chance, and thus obtain a statistically significant cumulative risk estimate in its meta-analysis of U.S. studies.

- A confidence interval measures the probability that a statistical association was obtained by chance. The net effect of lowering the confidence interval from 95% to 90% is to artificially double the likelihood of ruling out chance as a possible explanation.
- The EPA's use of a lower confidence interval cannot be justified scientifically in light of the following observations:

The EPA and other federal agencies have generally used 95% confidence intervals in other risk assessments that have relied upon epidemiologic studies.

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- Funded in part by the National Cancer Institute, the 1992 Brownson, et al., study is one of the largest studies ever conducted on ETS exposure and lung cancer incidence.<sup>60</sup> It was not included in the Risk Assessment.
- The EPA had access to the two studies well in advance of the release of the final Risk Assessment.
- If the two studies were included in the EPA's meta-analysis of U.S. studies, a statistically nonsignificant cumulative risk estimate for spousal smoking would be calculated, even at the 90% confidence interval used by the EPA.<sup>59</sup>
- The inclusion of both the studies in the meta-analysis should negate the classification of ETS as a Group A carcinogen, in that a cumulative risk estimate for the U.S. studies would not be statistically significant, even at the 90% confidence interval.<sup>59</sup> The Agency should have estimated no statistically significant increased risk for lung cancer, at either a 95% or a 90% confidence interval.
- A meta-analysis including the two recent studies was forwarded to the EPA more than one month prior to the release of the final Risk Assessment.<sup>59</sup> The EPA chose not to include those

spousal smoking and lung cancer; moreover, all six were conducted outside the United States.<sup>43,45,47,49,50,57</sup>

- These studies, as noted above for the U.S. studies, employed inconsistent methods of design and analysis.
- More importantly, the EPA failed to investigate whether the statistically significant associations reported in those studies could be the result of confounding by potential risk factors. The EPA failed to consider the large body of literature independent of the spousal smoking studies that addresses such factors.<sup>64-87</sup>
- EPA took the position that it was necessary to identify a single confounder, applicable across all the studies. Given the disparate study populations, methods, and analysis employed in the 30 studies, the identification of a single confounder to explain the reported association between spousal smoking and lung cancer is an unwarranted and, indeed, an unscientific expectation.<sup>74</sup>

Moreover, the scientific literature identifies several sources of possible bias in the spousal smoking studies.<sup>88-98</sup> These include publication bias, recall (exposure) bias, disease misclassification and smoking status misclassification.

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The "background adjustment" is questionable since it relies on selected exposure data.

Moreover, the background adjustment presumes a causal relation for spousal smoking and lung cancer.

In relying on the 30 spousal smoking studies, the EPA selectively chose which data to use. Specifically, the EPA limited examination to the reported association between spousal smoking status in females and lung cancer.

- Although 11 of the 30 epidemiologic studies considered by the EPA also assessed workplace exposures to ETS, the Risk Assessment did not address those data.<sup>31,33,35,37-39,47,48,51,54,58</sup>

Nine of the 11 spousal smoking studies that examined workplace exposures reported no statistically significant association with lung cancer.<sup>31,35,37,39,47,48,51,54,58</sup>

If the data on workplace exposure reported in the 11 studies are pooled in a meta-analysis such as the one conducted in the Risk Assessment, the summary risk estimate is not statistically significant.<sup>101</sup>

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The SAB Report noted that most of the epidemiologic studies evaluated for dioxin "do not provide definitive data" and should be classified as "inconclusive, due in most cases to design limitations such as inadequate power and inadequate exposure assessment."

The Report concluded that "without good exposure data, the epidemiologic studies are meaningless."

- The SAB Workshop Review Draft on diesel emissions stated:<sup>103</sup>

An excess risk of lung cancer was observed in three out of seven cohort studies and six out of seven case-control studies. Of these studies, two cohort and two case-control studies observed a dose-response relationship using duration of employment as a surrogate for dose. However, due to the lack of actual data on exposure to diesel exhaust in these studies and other methodologic limitations such as lack of latency analysis etc., the evidence of carcinogenicity in humans is considered to be limited for diesel exhaust exposure. (emphasis added)

The SAB Working Group report on EMF observed:<sup>104</sup>

The association between cancer occurrence and exposure to either ELF or RF fields is not strong enough to constitute a proven causal relationship, largely because the relative risks in the published reports have seldom exceeded 3.0 in both childhood residential exposures and in occupational situations. (emphasis added)

And:

The consistently repeated pattern of lymphoma, leukemia, nervous system cancer and lymphoma in childhood studies and the ruling out of several confounding exposure factors in the Savitz, et al. (1988) study argue in favor of a causal link between these tumor types in children and exposure to ELF magnetic or electric fields. However,

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- Data are presented in some of the spousal studies in such a way that permits comparison of exposure data (i.e., the number of cigarettes or duration of recalled exposure) with estimates of risk. Such data are amenable to what statisticians refer to as a "trend test."
- The EPA's analysis did not rely on the study data as reported. Instead, the authors of the Risk Assessment recalculated trends for dose-response by adding what statisticians call a "pseudo-datum" representing zero exposure.<sup>105</sup>
- The addition of the "pseudo-datum" converts the statistically non-significant dose-response trends originally reported in the individual studies into statistically significant trends.
- The use of this inappropriate procedure essentially permits the establishment of a dose-response trend based upon any single category of exposure greater than zero.<sup>105</sup>
- Such trends do not support the existence of a dose-response among exposed individuals, nor do they rule out the possibility that the claimed associations relied upon are attributable to confounding or other factors that are correlated with spousal smoking.

- Many of the studies of exposure to ETS constituents under realistic conditions in public places, workplaces and homes omitted from the Risk Assessment report minimal exposures to ETS: these reported exposures do not support the conclusions of the Risk Assessment.<sup>1,4-8,107-138</sup>
- The initial public review draft for the ETS Risk Assessment (1990) did not even contain an exposure assessment.

Comments submitted to the public docket for the 1990 draft risk assessment observed that the EPA had failed to provide an exposure assessment which considered data from the numerous published studies on actual levels of ETS constituents in the air of public places and workplaces.

- In apparent response to that criticism, the revised 1992 draft of the ETS Risk Assessment contained a chapter entitled "Estimation of Environmental Tobacco Smoke Exposure," but the chapter's authors failed to consider at least 35 pertinent exposure studies on ETS constituent levels in public places.

Furthermore, during its review of the chapter in July of 1992, the EPA's Science Advisory Board rejected the chapter and returned it to the author for rewriting.



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- Finally, it has been reported that because nicotine is largely present in the gas phase of ETS, measurement levels of its metabolite, cotinine, do not reflect exposures to other constituents that may be present, for example, in the particulate phase of ETS.
- For these reasons, cotinine should not be regarded as a reliable quantitative measure of ETS exposure.

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IN THE UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

FLUE-CURED TOBACCO COOPERATIVE  
STABILIZATION CORPORATION  
1304 Annapolis Drive  
Raleigh, North Carolina 27608

and

THE COUNCIL FOR BURLEY TOBACCO,  
INC.  
3070 Harrodsburg Road  
Lexington, Kentucky 40503

and

UNIVERSAL LEAF TOBACCO COMPANY,  
INC.  
1501 North Hamilton Street  
Richmond, Virginia 23230

and

PHILIP MORRIS INCORPORATED  
120 Park Avenue  
New York, New York 10017

and

R.J. REYNOLDS TOBACCO COMPANY  
401 Main Street  
Winston-Salem, North Carolina,  
27102

and

GALLINS VENDING COMPANY  
715 Stadium Drive  
Winston-Salem, North Carolina  
27101

Plaintiffs,

vs.

UNITED STATES ENVIRONMENTAL  
PROTECTION AGENCY  
401 M Street, S.W.  
Washington, D.C. 20460

Civil Action No. \_\_\_\_\_

2045671416

2. EPA's risk assessment of ETS, entitled "Respiratory Health Effects of Passive Smoking: Lung Cancer and Other Disorders" ("ETS Risk Assessment"), formally designates ETS as a Group A carcinogen, the highest carcinogenic designation under EPA's scheme for classifying suspect carcinogens. The classification of ETS as a Group A carcinogen was intended to and in fact did have a substantial impact throughout the country, including but not limited to compelling increased restrictions on smoking by private entities and all levels of government. EPA's actions with regard to ETS violated express statutory restrictions on its authority in the Radon Act and violated statutory commands to convene and consult with specific advisory committees.

3. EPA's classification of ETS as a Group A carcinogen is wrong as a matter of law and science and, as such, is arbitrary and capricious. As demonstrated in this Complaint EPA was able to reach its conclusion only by manipulating and "cherry-picking" data, ignoring critical statistical studies and chemical analyses, failing to account for confounding factors and sources of bias, violating basic statistical principles designed to minimize the possibility that an apparent association is due to chance, and generally altering EPA's models, assumptions, and methodologies when use of the Agency's usual models, assumptions, and methodologies would not have supported its conclusions. The classification of ETS and the underlying risk assessment violated

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place of business in Richmond, Virginia. Universal Leaf purchases leaf tobacco from growers, processes it and sells it to cigarette manufacturers.

8. Plaintiff Philip Morris Incorporated ("Philip Morris") is a Virginia corporation with its principal place of business in New York, New York.

9. Plaintiff R.J. Reynolds Tobacco Company ("Reynolds") is a New Jersey corporation with its principal place of business in Winston-Salem, North Carolina.

10. Plaintiffs Philip Morris and Reynolds at all times relevant to this action, were and continue to be engaged in the manufacture and distribution of cigarettes.

11. Plaintiff Gallins Vending Company ("Gallins") is a North Carolina corporation with its principal place of business in Winston-Salem, North Carolina. Gallins is engaged in the distribution of cigarettes through its placement and servicing of vending machines containing cigarettes in various retail and other establishments throughout the Winston-Salem, North Carolina area.

12. Plaintiffs have been and will continue to be directly affected and injured by defendants' unauthorized and unlawful decision to classify ETS as a human carcinogen.

13. Defendant EPA is an independent agency of the Executive Branch established by Congress to coordinate and implement

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18. EPA thus has no authority either (i) to regulate indoor air quality, or (ii) to take any action, other than research, in preparation for such regulation. For this reason, the final regulatory classification of ETS as a Group A carcinogen is beyond EPA's authority. Such classification serves only impermissible regulatory purposes and therefore is activity expressly prohibited by the Radon Act.

19. The Radon Act required EPA to establish two new committees "to assist [it] in carrying out the research program for radon gas and indoor air quality." The first committee, the "Federal Agency Advisory Committee," was to be composed of representatives from various federal agencies concerned with indoor air. The second committee, the "Radon Act Advisory Committee," was to be composed of representatives from the states, the scientific community, industry, and public interest organizations. In violation of the Radon Act, EPA has never established the Radon Act Advisory Committee.

20. Contrary to the requirements of the Radon Act, EPA initiated, prepared, and reviewed the ETS Risk Assessment without consulting with the Federal Agency Advisory Committee or, obviously, the Radon Act Advisory Committee.

21. As a result of EPA's violation of the requirements of the Radon Act, representatives from industry, the states, the scientific community, and public interest organizations were precluded from assisting EPA in the manner required by Congress.

expressed as relative risks. A relative risk is the ratio of the disease incidence rate in the exposed group to the incidence rate in the unexposed group. A relative risk of 1.0 indicates that the observed disease incidence rate in the exposed group is the same as that in the unexposed group. A relative risk above 1.0 indicates that the disease incidence rate is greater in the exposed group, while a relative risk less than 1.0 indicates that the disease incidence rate is smaller in the exposed group.

25. In recognition of the complexity of epidemiology and to ensure consistency in its methodology, EPA has adopted certain criteria by which it evaluates epidemiologic data. These criteria are set forth in EPA's own cancer risk assessment guidelines, "Guidelines for Carcinogen Risk Assessment," 51 Fed. Reg. 33992 (Sept. 24, 1986) (the "Risk Assessment Guidelines"). The Risk Assessment Guidelines provide that before a conclusion regarding whether an exposure causes a disease (a causal inference) can be based upon epidemiologic data, three criteria must be met: (i) the apparent statistical association must be unlikely to be produced by chance; (ii) the possibility of confounding (i.e. the role of other actual or potential factors in the apparent association) must have been considered and ruled out as an explanation for the association; and (iii) there must be no identified bias that could explain the apparent association. 51 Fed. Reg. 33999. In addition, EPA admits in its ETS Risk Assessment that epidemiologic data must also be assessed

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interval calculated with a 95% confidence level, for example, is referred to as a 95% confidence interval. An apparent association or relative risk is said not to be statistically significant at the 95% confidence level unless the entire range of the 95% confidence interval for that risk is above or below 1.0. By generally accepted scientific convention, a 95% confidence level is required in epidemiologic studies to judge an association as statistically significant.

28. EPA analyzed 30 published epidemiologic studies when classifying ETS as a Group A carcinogen. The studies primarily address whether a woman's risk of lung cancer may be statistically correlated with whether her spouse smokes. The studies do not measure actual ETS exposure. Instead, they rely on questionnaire responses as to whether a woman's spouse smokes, thereby treating reports of spousal smoking as a surrogate for actual or measured ETS exposure.

29. Of the 30 published ETS studies EPA relied upon, 11 were conducted in the United States. As originally reported, none of the U.S. studies found an overall risk estimate for lung cancer that was statistically significant.

30. Of the remaining studies conducted in seven countries other than the United States, 13 found no overall statistically significant association between spousal smoking and lung cancer as originally reported. Put another way, of the 30 studies reviewed by EPA, 24 -- a full 80% -- as originally reported do

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also gathered data on male lung cancer risk and spousal smoking and, of these, only one, a Japanese study by Hirayama that is methodologically flawed on other grounds, is statistically significant even at the lower confidence level. Twelve of fourteen reported studies that have examined workplace ETS exposure and lung cancer risk have reported no statistically significant association at the lower confidence level. Similarly, 12 of 13 studies that have examined childhood ETS exposure and adult lung cancer risk fail to show a statistically significant association at that level.

34. The large number of studies, both those considered by EPA and those EPA refused to consider, which report no overall statistically significant association between ETS and lung cancer, overwhelm the few studies that EPA claims demonstrate an association and suggest that those few results may simply be the result of chance. When this evidence is coupled with EPA's choice of a confidence level which doubles the risk of an association due to chance being labeled statistically significant, chance becomes the likely explanation for any statistical association claimed by EPA between ETS and lung cancer.

(ii) Confounding

35. Confounding of data exists when an association between a disease and an exposure to one agent can be explained, in whole or in part, by an exposure to a second agent that is associated



data. Instead, EPA deemed the criterion satisfied largely because it claimed to be unable to identify any single confounding factor that in itself would explain the apparent association between ETS and lung cancer which appeared in EPA's analysis. EPA's methodology falls well short of the Guidelines' requirement to "rul[e] out" the possibility of confounding.

(iii) Bias

39. Bias in statistics refers to any trend in the design, collection, analysis, interpretation or publication of statistical data that causes or may tend to cause a systematic distortion of the true nature of the relationship studied.

40. Both the Risk Assessment Guidelines and accepted epidemiologic principles require that bias must be excluded as an explanation for an observed association before it can be concluded that a statistically significant association exists. Various sources of bias, including publication bias and respondent bias, could explain any association claimed by EPA between ETS and lung cancer.

41. EPA recognized only one source of bias in its Risk Assessment -- the tendency of smokers to misrepresent themselves as nonsmokers ("smoking status misclassification bias") -- and chose to adjust for it by using an unpublished scientific model that contains numerous mathematical and conceptual inconsistencies, including assumptions based on nonrepresentative data. If EPA had used representative data, EPA's own analysis

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Risk Assessment, acknowledged the weakness of the association found by EPA when he noted to reporters at a press conference called to publicize the draft that the risk of ETS was "probably much less than you took to get here through Washington traffic."

45. In other contexts, EPA has concluded that relative risks greater than the risks claimed by EPA for ETS were insufficient to classify a potential carcinogen as a Group A carcinogen. For example, in a draft report on electromagnetic fields, the EPA concluded that, "[t]he association between cancer occurrence and exposure to either ELF or RF fields is not strong enough to constitute a proven causal relationship, largely because the relative risks in the published reports have seldom exceeded 3.0 in both childhood residential exposures and in occupational situations." U.S. EPA, Office of Health and Environmental Assessment, Evaluation of the Potential Carcinogenicity of Electromagnetic Fields, EPA/600/6-90/005A, Workshop Review Draft, June, 1990. The 1.19 relative risk reported for ETS by EPA is less than one-tenth of the 3.0 relative risk found "not strong enough" by the SAB with regard to electromagnetic fields.

46. Because any statistical associations between ETS and lung cancer relied upon by EPA are so weak, it is very likely that they are produced by chance, bias, or confounding.

causal inferences. Inconsistency among studies suggests that chance, bias, or confounding has produced the associations reported, not exposure to the substance under assessment.

52. The epidemiologic studies of spousal smoking and ETS are remarkably inconsistent. The studies' results vary widely by geographic area and the magnitudes of the reported associations vary by almost 300%. Without considering the requirement of statistical significance, six studies report associations above 2.0 while six studies report associations below 1.0. One study (Wu-Williams) reports a statistically significant negative association between ETS and lung cancer.

(b) EPA's Meta-Analysis of Epidemiologic  
Studies Provides No Basis for a  
Group A Classification

53. Recognizing that analysis of the individual epidemiologic studies could not support a Group A classification, EPA combined or pooled select portions of the data from the epidemiological studies using a controversial technique known as meta-analysis to create evidence of an association between lung cancer and ETS. This exercise not only did nothing to eliminate bias, confounding, and methodologic flaws in any of the individual epidemiologic studies, but it introduced new and different errors and flaws into the analysis.

54. First, relying solely on data regarding U.S. women and employing its unorthodox confidence level, EPA calculated a pooled relative risk estimate of 1.19 which is extremely weak.

b. EPA included certain reported data from an incomplete study (Fontham, 1991). Only the first three years of the five years scheduled have been completed and publication occurred before additional planned steps of verification had been undertaken. Although EPA included certain data from this incomplete study, it failed to include data relating to confounding factors which had been collected by the study's authors.

c. EPA violated its own criteria for determining what data to select with respect to one study (Janerich). Specifically, EPA used unadjusted risk estimates from household exposure from Janerich while it used adjusted risk estimates from spousal exposure from all other studies from which adjusted risk estimates could be derived.

57. Fourth, EPA failed to adjust adequately for smoking status misclassification bias, which is known to inflate the apparent association observed in studies of spousal smoking and lung cancer. Although EPA acknowledged this one source of bias and purported to adjust for it, EPA used a method of adjustment based on unrepresentative data instead of more representative data. EPA's use of these unrepresentative data resulted in an extremely low and unrealistic rate of adjustment that is not representative of the U.S. population for this crucial variable.

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(2) EPA Improperly Relied Upon a Proxy  
Substance to Justify Its Group A  
Classification

59. EPA also attempted to support its decision to classify ETS as a Group A carcinogen on an independent ground: analysis of a proxy substance. Specifically, EPA claimed that similarities between ETS and mainstream smoke (the smoke inhaled by a smoker), coupled with the assumption that any exposure to mainstream smoke poses a lung cancer risk, justified a Group A classification. EPA's classification on this basis is arbitrary and capricious.

60. First, EPA ignored the fact that ETS is not the equivalent of mainstream smoke. ETS is a highly dilute, complex and dynamic mixture of sidestream smoke ("SS"), exhaled mainstream smoke ("MS") and some diffused tobacco smoke emanating from the tobacco rod. Very few of the chemical constituents identified in mainstream smoke have been identified in ETS in ambient air. The general physical and chemical properties of the two smokes, including particle size, pH, constituent-phase distribution, and other physicochemical traits, differ significantly.

61. As recognized by the public health community, the multiple, pervasive and demonstrable differences between ETS and MS preclude any rational analysis of ETS using a proxy study of data on mainstream smoke. The Surgeon General concluded in 1986 that knowledge of MS chemical composition is of limited assistance in evaluating ETS: "Comparison of the relative

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a. Certain ETS constituents such as particulate matter and ambient nicotine can be measured in the ambient air. Based on those data, scientists have consistently estimated that an ETS exposed nonsmoker is exposed to the range of one to five cigarette equivalents per year.

b. According to a recent published review, data from several epidemiologic studies on active smoking suggest that smoking four to five cigarettes per day is not likely to be associated with a statistically significant increased risk of lung cancer.

c. Differences in retention can further expand these dosimetric differences. For example, it is estimated that the average ETS exposed person appears to retain between 10,000 and 100,000 times less smoke particulate matter than a cigarette smoker.

d. EPA's assumption, that no threshold exists for ETS exposure, relies solely on active smoking studies which have as their lowest exposure range 1-7, 1-9, 1-14 or <20 cigarettes smoked per day. All of these ranges are far in excess of the highest dose conceivably attributable to ETS.

65. Moreover, in the absence of a clear congressional mandate to the contrary, EPA is required to make a finding that a risk is significant before taking such action as classifying ETS as a Group A carcinogen. EPA's "no-threshold" assumption is an insufficient basis upon which to make such a finding. Indeed, if

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classifying potential carcinogens. Members of the general public, including plaintiffs, have a legitimate expectation that the guidelines will be followed and are justified in relying on them.

68. As set out above, EPA has violated the Risk Assessment Guidelines by failing to rule out the possibility that any association between spousal smoking and lung cancer is attributable to chance, confounders, or bias, and by failing to consider the absence of a strong association or a dose-response relationship. In addition, the EPA's classification of ETS as a Group A carcinogen violates the Risk Assessment Guidelines in at least six other respects.

69. First, the Risk Assessment Guidelines require EPA to ensure that "[s]tudies are evaluated according to sound biological and statistical considerations and procedures." 51 Fed. Reg. at 33994. EPA violated accepted statistical principles by performing a meta-analysis on noncomparable data and by using an unorthodox confidence level in place of the scientifically accepted 95% level. Moreover, EPA engaged in unjustified biological assumptions in applying studies on mainstream smoke to ETS.

70. Second, the Risk Assessment Guidelines require that the EPA's evidence from epidemiologic studies be "sufficient" before ETS can be classified as a Group A carcinogen. 51 Fed. Reg. at 34000. All of the epidemiologic studies conducted in the United

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on home exposure during childhood reported in 10 of the 30 studies, (iii) the data from numerous published studies which have measured ETS constituents in indoor air, (iv) the data on the physical and chemical distinctions between ETS and MS, and (v) data on identified sources of bias and confounding factors.

72. Fourth, the Risk Assessment Guidelines require the EPA to "fully present" all relevant scientific information in the ETS Risk Assessment. 51 Fed. Reg. at 33992. The ETS Risk Assessment fails to "fully present" critical scientific information. For example, the EPA has not informed the public of the fragility of the meta-analysis. That analysis depends entirely, among other things, on (1) the determination to evaluate chance at a lower confidence level; (2) the exclusion of the largest U.S. study ever; and (3) the employment of a series of unjustified assumptions and unproven and unaccepted methods.

73. Fifth, the Risk Assessment Guidelines require the EPA to "use the most scientifically appropriate interpretation to assess risk." 51 Fed. Reg. at 33992. EPA did not. Instead, EPA used an unconventional statistical significance level, combined noncomparable studies in a meta-analysis, relied upon inappropriate assumptions to manipulate the data, such as when adjusting for smoker misclassification, and inappropriately analogized ETS exposure to cigarette smoking. Had EPA employed "the most scientifically appropriate interpretation" of the available data, it could not have classified ETS as a Group A carcinogen.



(2) Exposure Assessment Guidelines

77. In 1992, the EPA issued its Exposure Assessment Guidelines, which govern EPA exposure assessments and their use in risk assessments. Like the Risk Assessment Guidelines, the purposes of the Exposure Assessment Guidelines are "to promote consistency and technical quality in risk assessment, and to ensure that the risk assessment process is maintained as a scientific effort separate from risk management." 57 Fed. Reg. at 22888.

78. The ETS Risk Assessment violated the Exposure Assessment Guidelines in at least three respects.

a. First, the Exposure Assessment Guidelines require that "exposure estimates along with supporting information . . . be fully presented in Agency risk assessment documents." 57 Fed. Reg. at 22888. Numerous studies providing ETS exposure estimates are omitted from the Risk Assessment.

b. Second, the Exposure Assessment Guidelines direct EPA to "identify the strengths and weaknesses of each assessment by describing uncertainties, assumptions, and limitations, as well as the scientific basis and rationale for each assessment." 57 Fed. Reg. at 22888. EPA made no effort to identify the numerous uncertainties, assumptions and limitations of its exposure assessment, including the

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D. Classification of ETS as a Group A  
Carcinogen Constitutes Final Agency Action

80. In classifying and publicizing ETS as a Group A carcinogen, EPA expected and intended its action to have a substantial regulatory impact resulting in the restriction of smoking in the workplace and in public. Then-EPA Administrator Reilly stated that classifying ETS as a human carcinogen was "one of the biggest decisions I ever will make." He expressed the hope that the classification "will have profound reverberations in the country" and that no further action by any other government agency will be necessary for the EPA report to have an impact because "the liability question will drive it." Mr. Reilly concluded that "the government has spoken on the question."

81. EPA's decision to classify ETS as a Group A carcinogen has resulted in and continues to result in exactly the regulatory impact intended by EPA. By classifying ETS as a human carcinogen, EPA exerted tremendous pressure on both private and public entities to restrict smoking in the workplace and in public -- pressure that the entities believed could not be ignored. Specifically, as a direct result of the EPA's classification of ETS as a Group A carcinogen, private entities, fearing liability, have felt compelled to institute restrictions or total bans on smoking in their buildings. The ETS Risk Assessment also has prompted public agencies to institute or consider instituting similar smoking restrictions or bans.

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a. EPA intended that its January 7, 1993, classification of ETS as a Group A carcinogen be a final and unequivocal agency conclusion and decision. As Administrator Reilly stated, "[t]he government has spoken on the question."

b. The ETS Risk Assessment embodying the classification was formally released by the EPA administrator.

c. EPA is contemplating no further action regarding the classification of ETS as a Group A carcinogen.

## E. Plaintiffs Have Been Injured By EPA's Actions

86. The classification of ETS as a Group A carcinogen was intended to and in fact did falsely disparage plaintiffs' products and their reputations and resulted in a loss of good will. The classification also was intended to and in fact did result in the imposition of greater smoking restrictions in the workplace and public areas. These smoking restrictions, based on a classification of ETS as a Group A carcinogen without scientific foundation, have resulted and will continue to result in decreased sales and use of cigarettes and, concomitantly, decreased use and sales of tobacco. For example, plaintiff Gallins has removed cigarette vending machines from premises where they had been placed at the request of the owners of the premises. On information and belief, it has also been precluded

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now that the [EPA] has declared that secondhand smoke causes cancer."

c. Restaurants have also initiated smoking bans. For example, in specific reliance on EPA's classification, the California Restaurant Association, on January 7, 1993, endorsed legislation which would ban smoking in the workplace and all public places.

d. The Board of Directors of the Building Owners and Managers Association International, representing more than 5 billion square feet of North American office space, passed a resolution supporting a federal ban on smoking in the workplace.

e. The Governors of Kentucky and California have already issued executive orders that make those states' public smoking laws more restrictive. Other states, including Colorado, Delaware, Hawaii, Illinois, Iowa, Kansas, Maryland, Missouri, Minnesota, Montana, Nebraska, New York, Ohio, Texas, Utah, Vermont, and Virginia have proposed legislation to ban or restrict smoking in workplaces and other public areas.

f. Legislation was introduced in Congress that would prohibit smoking in all structures owned or leased for use by a federal agency, including the Executive and Judicial Branches, "Preventing Our Federal Building Workers and visitors Exposure to Deadly Smoke (PRO-FEDS) Act of 1993."

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93. Classification of ETS as a Group A carcinogen does not constitute research as authorized by the statute. EPA's classification of ETS as a Group A carcinogen serves no legitimate research purpose, but is designed and intended solely to achieve a substantial regulatory impact and effect. EPA's classification of ETS has in fact had a substantial regulatory impact and effect.

94. EPA exceeded its statutory authority under Sections 403 and 404 of the Radon Act by classifying ETS as a Group A carcinogen.

95. EPA further exceeded its authority under the Radon Act by deciding to classify ETS as a Group A carcinogen without making a finding as to whether exposure to ETS poses a significant risk.

96. EPA also violated the Radon Act by not properly establishing the Radon Act Advisory Committee mandated by Section 403(c) of the Radon Act. Under the Radon Act, that Committee is to provide EPA with the input from industry and the public to assist the defendants in carrying out research programs. Because no such committee was ever formed, EPA's classification of ETS and the ETS Risk Assessment also violate the Radon Act and exceed EPA's statutory authority.

97. Under Section 403(c) of the Radon Act, the Administrator was also required to establish a Federal Agency Advisory Committee composed of individuals representing Federal

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Advisory Committee are unlawful because they are in excess of the authority of the defendants;

(C) To declare that the classification of ETS as a Group A carcinogen and the issuance of the ETS Risk Assessment were unlawful and in violation of statutory procedures;

(D) To grant an injunction requiring EPA to withdraw its classification of ETS as a Group A carcinogen and to withdraw its ETS Risk Assessment; and

(E) To grant plaintiffs such additional relief that the Court may deem just and proper.

**COUNT II**

**THE CLASSIFICATION OF ETS AS A GROUP A  
CARCINOGEN IS ARBITRARY, CAPRICIOUS,  
AND OTHERWISE NOT IN ACCORDANCE WITH LAW**

100. Plaintiffs incorporate herein by reference paragraphs 1 through 88 of the complaint.

101. EPA's decision to classify ETS as a Group A carcinogen and the underlying ETS Risk Assessment was based on incomplete, irrelevant, and inconsistent data.

102. In classifying ETS and promulgating the ETS Risk Assessment, EPA ignored available, persuasive scientific data contrary to its conclusions.

103. The classification of ETS as a Group A carcinogen and the ETS Risk Assessment are based on models, assumptions, and methodologies that are inaccurate, flawed, and not accepted by the scientific community.

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COUNT III

EPA VIOLATED THE APA BY FAILING  
TO COMPLY WITH ITS OWN GUIDELINES

107. Plaintiffs incorporate herein by reference the allegations contained in paragraphs 1 through 88 of this complaint.

108. In classifying ETS as a human carcinogen, EPA violated the Risk Assessment Guidelines.

109. In classifying ETS as a human carcinogen, EPA violated the Exposure Assessment Guidelines.

110. EPA violated its own guidelines as alleged above, individually and collectively, for the purpose of reaching a desired conclusion (that ETS is a Group A carcinogen) that could not have been reached but for such violations.

111. As a result of EPA's violations of its own guidelines, the classification of ETS as a Group A carcinogen was "without observation of procedure required by law" and therefore violated Section 706(2)(D) of the APA.

112. As a direct and proximate cause of EPA's unlawful acts, plaintiffs have been seriously injured as alleged herein.

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116. In classifying ETS as a Group A carcinogen and issuing the ETS Risk Assessment, EPA also violated its Risk Assessment Guidelines, and its Exposure Assessment Guidelines.

117. Plaintiffs had a legitimate expectation that EPA would comply with the Radon Act and with EPA's own guidelines. Plaintiffs relied on the provisions of the Radon Act and EPA's guidelines for protection from arbitrary and capricious actions, including classification of ETS as a Group A carcinogen and the underlying risk assessment.

118. EPA was only able to reach its desired conclusion by violating the Radon Act and the agency's guidelines. EPA could not have concluded that ETS was a Group A carcinogen but for such violations.

119. As a direct and proximate cause of EPA's violations of the Radon Act and the agency's guidelines, plaintiffs have been seriously injured and deprived of property interests, including but not limited to loss of good will and sales.

WHEREFORE, plaintiffs pray this Court grant plaintiffs the following relief:

(A) To declare that EPA's classification of ETS as a Group A carcinogen and the ETS Risk Assessment violate the guarantee of due process of law in the United States Constitution, U.S. Const. amend. V.;



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FOR IMMEDIATE RELEASE  
February xx, 1994

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## **MEDIA ADVISORY**

### **FEDERAL COURT RULES EPA IMMUNE FROM JUDICIAL REVIEW Tobacco Group is Considering Appeal**

**Who:**

**What:**

Discuss the federal court's dismissal of a lawsuit that sought to have the EPA's report on environmental tobacco smoke (ETS) declared null and void. The case, filed by a group of tobacco growers and businesses in June 1993, was dismissed on the grounds that the EPA is immune from judicial review. The tobacco group is considering an appeal.

**When:**

**Where:**

2045671442

2045671443

FOR IMMEDIATE RELEASE  
February xx, 1994

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## MEDIA ADVISORY

EPA MOTION TO DISMISS LAWSUIT REJECTED BY FEDERAL COURT  
Tobacco Group Comments on Victory

Who:

What:

Discuss a federal court's rejection of the EPA's motion to dismiss a lawsuit filed by a group of tobacco growers and business in June of 1993. The lawsuit seeks to have the agency's report on environmental tobacco smoke declared null and void.

When:

Where:

2045671444

VIII VNR TRANSCRIPT  
WIN

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**SUGGESTED ANCHOR LEAD**

Today a federal court in Winston Salem, N.C., rejected a motion filed by the EPA to dismiss a lawsuit filed against the agency, that sought to have the agency's report on environmental tobacco smoke overturned. Mike Morris has the details

Narration over shots of EPA presser from Jan. '93

WHEN THE EPA RELEASED ITS REPORT ON THE ALLEGED HEALTH RISKS OF ENVIRONMENTAL TOBACCO SMOKE IN JANUARY OF 1993, IT WAS CONDEMNED BY THE TOBACCO INDUSTRY AND SCORES OF LEADING SCIENTISTS.

Dissolve to shots from PM presser

Steve Parrish on camera (from 1/93 presser

Let's be very clear here. The risk assessment is based on such a fragile house of cards that if it dealt with anything other than tobacco, many of you would have already ripped it apart, and the EPA would have buried it in embarrassment.

Dr. Gio Gori

The EPA report on ETS does not conform to scientific standards if for no other reasons, because it uses data that support their position and ignores all contrary data. If in fact, if the report were a scientific dissertation for a Doctoral degree, say, it would be rejected by any academic panel in this country.

Dissolve to shots of June presser

SO, LAST JUNE, 6 ORGANIZATIONS- INCLUDING VENDING MACHINE OPERATORS, TOBACCO GROWERS AND TOBACCO COMPANIES- RESPONDED BY FILING A LAWSUIT AGAINST THE EPA. THEY ASKED THAT THE RISK ASSESSMENT BE DECLARED NULL AND VOID. THE PLAINTIFFS CLAIMED THE EPA:

Dissolve to documents that darkens and chyrons pull out chyrons of bullet points

- USED FAULTY SCIENCE AND IMPROPER PROCEDURES
- MANIPULATED DATA
- AND IGNORED RECENT REPORTS THAT CONTRADICTED ITS CONCLUSION

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Dissolve to exterior of EPA and then to cover of the audit. It opens, darkens and chyron prints out points

WHILE THIS IS THE FIRST LAWSUIT OF ITS KIND AGAINST THE EPA, THE AGENCY'S USE OF SCIENCE HAS COME UNDER FIRE IN THE PAST. IN FACT, FORMER EPA ADMINISTRATOR, WILLIAM REILLY WAS SO CONCERNED HE DEMANDED AN AUDIT OF THE AGENCY'S PRACTICES AND POLICIES. RELEASED IN 1992, THE AUDIT FOUND THAT:

- "EPA SCIENCE IS OF UNEVEN QUALITY
- "THE AGENCY'S POLICIES AND REGULATIONS ARE FREQUENTLY PERCEIVED AS LACKING A STRONG SCIENTIFIC FOUNDATION"
- AND "EPA SCIENCE IS PERCEIVED BY MANY PEOPLE...TO BE ADJUSTED TO FIT POLICY."

Announcement day video-documents, court exteriors, etc.

TODAY'S RULING THAT REJECTS EPA'S MOTION TO DISMISS THE SUIT, MOVES THE CASE FORWARD. ALTHOUGH THE EPA STANDS BY ITS RISK ASSESSMENT, THE PLAINTIFFS, ENCOURAGED BY TODAY'S RULING, EXPECT TO PREVAIL WHEN THE CASE COMES TO TRIAL NEXT SOMETIME IN 1994.

Bob Weber on camera

The court's ruling allows us now to focus on the merits of the case. In a court of law, EPA must rely on science and evidence and not just on its own descriptions of its policy preference. We look forward to the opportunity to have this case determined on its merits in court.

WHILE THE EPA HOPED ITS RISK ASSESSMENT WOULD BE THE LAST WORD ON ENVIRONMENTAL TOBACCO SMOKE, THIS ISSUE WILL BE DECIDED IN A COURT LAW, INSTEAD OF THE COURT OF PUBLIC OPINION.

THIS IS MIKE MORRIS REPORTING

2045671447



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SUGGESTED ANCHOR LEAD-IN

Today the federal district court in Winston Salem, NC. announced that they were dismissing a lawsuit filed against the EPA by tobacco companies seeking to have the agency's report on environmental tobacco smoke overturned. Mike Morris has the details

Narration over exterior of EPA  
Dissolve to cover of report that softens and freezes to reveal chyrons listing points:

- EPA use of faulty science and improper scientific procedure
- Manipulation of date
- Failure to use recent studies that contradicted EPA's conclusions

LAST JUNE, 6 ORGANIZATIONS FILED SUIT AGAINST THE ENVIRONMENTAL PROTECTION AGENCY, ASKING THAT THE EPA'S REPORT ON ENVIRONMENTAL TOBACCO SMOKE, BE DECLARED NULL AND VOID. THE PLAINTIFFS CITED THE AGENCY'S USE OF FAULTY SCIENCE AND IMPROPER SCIENTIFIC PROCEDURES, MANIPULATION OF DATA, AND FAILURE TO CONSIDER RECENT STUDIES THAT CONTRADICTED ITS CONCLUSIONS. UPON ITS RELEASE IN JANUARY OF 1993, THE REPORT WAS CONDEMNED BY SCORES OF LEADING SCIENTISTS

Dr. Gio Gori  
(existing soundbite from June)

The EPA report on ETS does not conform to scientific standards if for no other reason because it uses data that support their position and ignores all contrary data. In fact, if the report were a scientific dissertation for a Doctoral degree it would be rejected by any academic panel in this country.

DESPITE THE REACTION FROM THE SCIENTIFIC COMMUNITY, THE COURT'S DISMISSAL OF THE SUIT TEMPORARILY PREVENTS JUDICIAL REVIEW OF THE EPA'S CONDUCT.

Steve Parrish on camera

If this ruling is allowed to stand what that means is that a judge will not be able to look at the facts in the case: the fact that EPA ignored 2 very recent large studies that were inconsistent with the EPA's results; the fact that 80% of the studies EPA did look at were inconsistent with the claims EPA has made and the fact that in the middle of the process EPA changed its own methodology in order to get to the conclusion it wanted to get to.

Dissolve to EPA shots-logo and interiors

Dissolve to shot of Reilly at the podium  
(from January presser)

Dissolve in cover of report-it opens and  
chyrons reveal:

- "EPA science is of uneven quality"
- "The agency's policies and regulations  
are frequently perceived as lacking a  
strong scientific foundation"
- "EPA science is perceived by many  
people both inside and outside the  
agency to be adjusted to fit policy"

THE AGENCY HAS A HISTORY OF  
CONTROVERSIAL SCIENTIFIC FINDINGS.  
IN FACT, FORMER EPA ADMINISTRATOR,  
WILLIAM REILLY, WAS SO CONCERNED  
ABOUT THE AGENCY'S USE OF SCIENCE  
THAT HE DEMANDED AN AUDIT OF THE  
AGENCY'S PRACTICES AND POLICIES. THE  
REPORT RELEASED IN 1992, WAS  
EXTREMELY CRITICAL OF THE AGENCY IN  
MANY KEY AREAS - FINDING THAT:  
"EPA SCIENCE IS OF UNEVEN QUALITY,  
AND THE AGENCY'S POLICIES AND  
REGULATIONS ARE FREQUENTLY  
PERCEIVED AS LACKING A STRONG  
SCIENTIFIC FOUNDATION...AND "EPA  
SCIENCE IS PERCEIVED BY MANY PEOPLE,  
BOTH INSIDE AND OUTSIDE THE AGENCY,  
TO BE ADJUSTED TO FIT POLICY. "

IRONICALLY, THAT'S EXACTLY THE BASIS  
OF THE ETS LAWSUIT, THAT THE EPA'S  
CLAIMS LACK A STRONG SCIENTIFIC  
FOUNDATION. IN FACT, THE AGENCY DID  
NO CLINICAL OR LABORATORY RESEARCH  
FOR ITS REPORT. INSTEAD, ITS RISK  
ASSESSMENT WAS BASED ON A REVIEW  
OF 30 STUDIES CONDUCTED IN THE 1980S.  
80% OF THOSE STUDIES FAILED TO  
SUPPORT EPA'S CONCLUSIONS. ONLY BY  
MANIPULATING DATA COULD EPA MAKE  
ITS CLAIMS. IN ADDITION, THE AGENCY  
ALSO IGNORED ONE OF THE LARGEST AND  
MOST RECENT ETS STUDIES, CONDUCTED  
BY THE NATIONAL CANCER INSTITUTE,  
THAT SHOWED NO STATISTICALLY  
SIGNIFICANT ASSOCIATION BETWEEN THE  
ETS AND LUNG CANCER.

Bob Weber on camera

The court has decided not to review the merits of  
our case at this time. And the case has been  
dismissed on a technicality.

**DRAFT**

Continue Weber

We're considering an appeal because the EPA admitted that it undertook no independent research whatsoever on environmental tobacco smoke, and because we believe that when a court does review the merits of this case, EPA's action will be exposed for what it is: EPA policy and not sound science.

Shots of plaintiffs press conference

WITH THE PLAINTIFFS VOWING TO  
CONTINUE THEIR FIGHT TO OVERTURN  
THE EPA REPORT, THIS CASE IS FAR FROM  
OVER.

THIS IS MIKE MORRIS REPORTING

X GERNERAL RELEASE  
RADIO ACTUALITY  
TRANSCRIPT-WIN

2045671452

DRAFT

# news/broadcast NETWORK

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## TRANSCRIPT

### EPA/Win Scenario -- General release

A FEDERAL DISTRICT COURT HAS REJECTED A MOTION FILED BY THE EPA TO DISMISS A LAWSUIT BROUGHT AGAINST THE AGENCY BY A GROUP OF TOBACCO GROWERS AND BUSINESSES. THAT LAWSUIT, WHICH NOW GOES TO TRIAL, SEEKS TO HAVE THE EPA'S REPORT ON ENVIRONMENTAL TOBACCO SMOKE DECLARED NULL AND VOID. ROBERT WEBER IS AN ATTORNEY IN THE CASE.

"We're delighted by this ruling which forces EPA to defend its conduct, in court. In a court of law, rules of science and evidence will control, not EPA's predetermined and biased policies."

THE EPA HAS BEEN CHARGED WITH MANIPULATING SCIENTIFIC DATA AND OVERSTEPPING ITS REGULATORY AUTHORITY. STEVE PARRISH, SENIOR VICE PRESIDENT AND GENERAL COUNSEL FOR PHILIP MORRIS U.S.A., A PLAINTIFF IN THE CASE.

"EPA ignored its own guidelines and manipulated data in order to get a predetermined conclusion. That's wrong as a matter of law and as a matter of science. The court's decision today is the first step in setting the record straight and we look forward to a trial on the merits."

I'M JAMES HILL.

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XI TOBACO STATES RADIO  
ACTUALITY TRANSCRIPT  
WIN

2045671454

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**TRANSCRIPT**

**EPA/Win Scenario -- Tobacco States**

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THE EPA HAS BEEN CHARGED WITH MANIPULATING SCIENTIFIC DATA AND OVERSTEPPING ITS REGULATORY AUTHORITY. FRED BOND OF THE FLUE-CURED TOBACCO COOPERATIVE STABILIZATION CORPORATION, A PLAINTIFF IN THE CASE.

"The livelihood of tens-of-thousands of tobacco farmers should not be subjected to the political whims of a government agency. We are pleased by the court's decision and we hope our lawsuit will end the EPA's practice of basing public policy on politics rather than sound science."

I'M JAMES HILL.

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XII GENERAL RELEASE  
RADIO ACTUALITY  
TRANSCRIPT-LOSS

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## TRANSCRIPT

### EPA/Loss Scenario -- General Release

IN JUNE A GROUP OF TOBACCO GROWERS AND BUSINESSES FILED SUIT AGAINST THE E-P-A, ASKING THAT ITS REPORT ON ENVIRONMENTAL TOBACCO SMOKE BE DECLARED NULL AND VOID. THE EPA WAS CHARGED WITH MANIPULATING SCIENTIFIC DATA AND OVERSTEPPING ITS REGULATORY AUTHORITY. STEVE PARRISH IS SENIOR VICE PRESIDENT AND GENERAL COUNSEL OF PHILIP MORRIS U.S.A., A PLAINTIFF IN THE SUIT

"EPA ignored its own guidelines and manipulated data to get the conclusions that it wanted to get. That's wrong as a matter of law and as a matter of science."

ALTHOUGH A FEDERAL DISTRICT COURT RULED IN FAVOR OF THE EPA'S MOTION CLAIMING IMMUNITY FROM JUDICIAL REVIEW, THE PLAINTIFFS ARE CONSIDERING AN APPEAL. ATTORNEY ROBERT WEBER.

"The court's ruling is strictly technical in nature. If and when we can force EPA to face the merits of our case in court, we're confident that EPA's conduct will be exposed for what it is, predetermined EPA policy and not sound science."

I'M JAMES HILL.

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**XIII TOBACCO STATES  
RADIO ACTUALITY  
TRANSCRIPT -LOSS**

**2045671458**

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**TRANSCRIPT**

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"Without question, the EPA's report jeopardizes the future of tens-of-thousands of tobacco farmers. The EPA can not be allowed to continue making public policy decisions based on politics rather than science."

A FEDERAL DISTRICT COURT RULED IN FAVOR OF THE EPA'S MOTION CLAIMING IMMUNITY FROM JUDICIAL REVIEW. THE PLAINTIFF'S ATTORNEY ROBERT WEBER.

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I'M JAMES HILL.

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# DRAFT

EPA/litigation/win op-ed/version #1  
approx. 650 words

Hardly a week goes by in this nation without a county, city, business or public facility implementing a smoking ban.

In 1993 alone, more than 300 shopping malls across the country banned smoking; several major airports, including Dallas-Ft. Worth, Atlanta Hartsfield International and National in Washington, D.C., went smoke-free; Amtrak banned smoking on all Metroliner trains; and the U.S. Postal Service implemented a smoking ban in all facilities. In addition, Los Angeles has banned smoking in all restaurants and the entire state of Vermont was declared smoke-free.

What is the common thread linking all these actions together?

In almost every instance, the U.S. Environmental Protection Agency's (EPA) report classifying environmental tobacco smoke (ETS) as a known human carcinogen has been cited as the primary basis for the bans.

While the elected officials and employers implementing the smoking bans no doubt had the welfare of citizens and employees in mind, it is unfortunate -- to say the least -- that these good intentions are misguided by a government agency interested in making popular, rather than good, public

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# DRAFT

policy.

And while tobacco is, and more than likely always will be, a controversial subject in this nation, it is a national disgrace that the livelihoods of tens of thousands of tobacco farmers, as well as the economic viability of countless businesses across the country, should be jeopardized by the actions of an agency motivated by the political rather than the scientific.

In issuing its report on ETS in January 1993, the EPA manipulated scientific data, ignored its own scientific guidelines and blatantly overstepped its regulatory authority. Ignored, for example, was the fact that 24 of the 30 worldwide studies the EPA reviewed failed to show a statistically significant increased risk between ETS and lung cancer. Further, of the 11 studies conducted in the United States and mentioned in the EPA's report, not one, as originally reported, found a statistically significant increased risk. And the agency also failed to include in its report data from one of the largest U.S. studies ever conducted on ETS. The study, which was sponsored by the National Cancer Institute, found no statistically significant association between ETS and lung cancer.

Unfortunately, ignoring scientific guidelines and basing decisions on political ideology rather than scientific data is

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# DRAFT

nothing new for the EPA. The agency has a long history of questionable decisions and policies. Just ask the apple growers in Washington state or the citizens of Times Beach, Missouri, past victims of the EPA's politically correct but scientifically flawed agenda.

That's why a group of six organizations representing tobacco growers and businesses joined together in June of last year to bring suit against the EPA. The lawsuit, which was filed in the U.S. District Court for the Middle District of North Carolina, asked the court to declare the agency's report on ETS null and void, and to find that the EPA had exceeded its statutory authority in issuing the report.

The EPA moved to have the case dismissed, claiming immunity from judicial review. In filing its motion, the agency asked the court to ignore the merits of the case, and argued that the court had no authority to review the legality of its actions.

On (date), the court dismissed the EPA's claim and the lawsuit now goes to trial. It is fortunate -- not only for those whose future depend upon tobacco, but for our nation as a whole -- that the EPA's attempt to avoid scrutiny was rejected. Americans can no longer afford to have their lives or businesses dictated to by a government agency guided by political whims, rather than facts. We as a nation should

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# DRAFT

look forward to the day the case goes to court -- where the evidence will be reviewed on the basis of merit, not by what is politically popular at the moment.

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# DRAFT

PA/litigation/win op-ed/version #2    PENDING LEGAL APPROVAL  
Approx. 650 words

In January 1993, the U.S. Environmental Protection Agency (EPA) issued its report on environmental tobacco smoke (ETS), classifying ETS as a "Group A" carcinogen.

Coincidentally, the U.S. General Accounting Office (GAO) issued a study evaluating the EPA that same month. In its report, the GAO cited inadequate and poorly managed scientific data among the many problems facing the EPA and noted the difficulties that arise when public policy is "dominated by public perceptions of risk rather than by scientific and expert judgment."

The EPA's report on ETS is an illustration of the problems articulated by the GAO. In conducting the report, the EPA manipulated scientific data, ignored its own scientific guidelines and blatantly overstepped its regulatory authority. Ignored, for example, was the fact that 24 of the 30 worldwide studies the EPA reviewed failed to show a statistically significant increased risk between ETS and lung cancer. Further, of the 11 studies conducted in the United States and mentioned in the EPA's report, not one, as originally reported, found a statistically significant increased risk. And the agency also failed to include in its report data from one of the largest U.S. studies ever conducted on ETS. The study, which was sponsored by the National Cancer Institute, found no

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# DRAFT

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While tobacco is, and more than likely always will be, a controversial subject in this nation, it is a national disgrace that the livelihoods of tens of thousands of tobacco farmers, as well as the economic viability of countless businesses nationwide, should be jeopardized by the actions of an agency motivated by the political rather than the scientific.

Fortunately, basing decisions on political ideology rather than scientific data is nothing new for the EPA. The agency has a long history of questionable decisions and policies. It asks the apple growers in Washington state or the citizens of Times Beach, Missouri, past victims of the EPA's

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XVI OP-ED -LOSS

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XVII

**CONTACT  
INFORMATION**

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# DRAFT

EPA/litigation/loss op-ed/version #1  
approx. 650 words

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Although the court ruled in favor of the EPA's claim (date), its decision in no way validates the agency's report -- it simply removes the EPA's actions from judicial review for the time being. We are strongly considering an appeal.

Americans, however, can no longer afford to have their lives or businesses dictated to by a government agency guided by

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2045671478

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